REMARKS

Claims 1, 14, and 15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner objected to the phrase "guiding the placement or observing the operation" of an invasive medical device on the grounds that these are different actions and it is not clear which action the claims are directed to. It is respectfully submitted that it is clear that the claims are directed to both actions, since they are both parts of a typical invasive procedure and are overlapping. For instance, if a surgeon is inserting a needle into the body to biopsy a target pathology, an embodiment of the present invention can be used to observe the needle as it is inserted and adjust its path of insertion so that it intersects the target pathology. The operation of the needle insertion is observed and the surgeon uses this visualization to guide the needle. Nevertheless, the claims in question have been amended to simplify this phrase and overcome this rejection.

The Examiner has correctly noted that the remaining reference numeral "(130)" in Claim 9 was an oversight and it has been deleted.

Claims 1-5, 10-12 and 14-19 were rejected under 35 U.S.C. §102(e) as being anticipated by US patent appl. pub. 2002/0049375 (Strommer et al.) Amended Claim 1 describes a method of observing the operation of an invasive medical device comprising operating an invasive medical device from an invasive medical device system to perform an activity within a body; operating an ultrasonic diagnostic imaging system to observe the invasive medical device by means of a real time three dimensional ultrasonic image; producing information with the invasive medical device system having coordinate information relating to the activity; and merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information. An embodiment of the present invention merges the location of an invasive device into real time three dimensional ultrasonic images of the region in the body where a procedure is being performed. With an ultrasound system of the present invention, a surgeon can observe an invasive medical procedure in real time in the volume of tissue in which the procedure is performed. Being able to follow the manipulation of an instrument in real time, such as an electrophysiology probe, is particularly important in cardiac procedures, since the heart is continually beating and moving in the chest cavity. Without real time imaging the surgeon cannot accurately guide, place, or manipulate a surgical instrument with the necessary precision.

The Examiner noted applicants' preliminary amendment in the Office action and has seen that the real time aspect of the present invention is highlighted in the claims. The system of Strommer et al. does not use real time imaging. It uses "live" imaging, but not real time imaging. What Strommer et al. do is assemble a sequence of 3D images over a period of time. Each of the 3D images is of the heart at a particular phase ("activity-state") of the heart cycle. The images are assembled from a large number of 2D images acquired with ECG heart gating by a two dimensional image acquisition device 104. Strommer et al. assemble a 3D image for each of nineteen successive phases (p_0-p_{18}) of the heart cycle. After the nineteen 3D images are acquired they are stored for later use and updated by adding more two dimensional images to them. The stored sequence of 3D images, referred to in diagnostic imaging as a "loop," can be repetitively replayed to show the recorded motion of the heart over and over again. Strommer et al. then begin their invasive procedure with a surgical tool 120 and detect its location in the body with a number of MPS sensors 162. During the procedure the patient's ECG is acquired in real time and used to select the previously assembled 3D images in synchronism with the current phases of the ECG signal. The sensed location of the surgical tool from the MPS system 108 is superimposed over the loop images as they are replayed. What is actually happening is that previously acquired 3D images of the heart are replayed in synchronism with the current phases of the patient's heart. Strommer et al. refer to this as a "pseudo real-time simulation" of what the heart is actually doing. See paragraph [0123]. The ECG is in real time and the location information of the surgical tool is presumably in real time, but they are used in a display of 3D images which are not in real time images but were acquired in the past. What the surgeon sees is a "live" sequence (the heart motion is seen), but it is past motion of the heart, not current (real time) motion of the heart at the time of the procedure. Since Strommer et al. do not use real time 3D images or tell how to do real time 3D imaging, the Strommer et al. application cannot anticipate the present invention.

The Strommer et al. application provides sufficient detail to appreciate how non-real time their "pseudo real-time simulation" is. They acquire 3D images for eighteen phases (p_0-p_{18}) of the heart (ECG) cycle [0137]. The normal heart rate of an individual at rest is about 60 bpm, which means that an average ECG cycle is one second. During each ECG they acquire eight two-dimensional images [0137]. Two of the phases are the same, so they can acquire one 2D image for each of the eighteen 3D images in two seconds. FIG. 5A shows the 2D images 190 of four of the 3D images after six 2D images have been acquired for each 3D image. The time needed to do this is 2 seconds times 6 images per heart phase,

which is 12 seconds. But six images is not nearly enough to render an accurate volumetric image. The typical 2D image has 128 lines, the X dimension, each of which extends to a depth Y. For 3D the number of images in the stack (see FIG. 5A) is the Z dimension. Since users will want the image resolutions in all dimensions to be the same, this means that the distance between each image in the stack (the Z dimension) must be the same distance as the line spacing in the X dimension. They must also be sufficiently close together to satisfy the Nyquist criterion for spatial sampling, which is less than the distance traveled by one cycle of the ultrasound signal at the frequency being used. A reasonable assumption is that the volume is the same size in both the X and Z dimensions, which means that 128 images in the Z dimension are needed. Let us assume that 120 images are used. But Strommer et al. say they interpolate some of the data [0157], which they can do and still satisfy the Nyquist criterion after 60 images are acquired; they can acquire the odd-numbered images and interpolate the even-numbered image data in between. For sixteen ECG phases and 60 images for each phase, Strommer et al. require 960 images. At an acquisition rate of eight images per second (per ECG cycle; [0137], this will take 120 seconds, or two minutes. This means that the average age of the 3D images at the moment they are initially assembled is one minute, an age which can be maintained (hopefully) by updating at the same acquisition rate.

Other problems are not addressed, such as how one can hold the ultrasound imaging probe absolutely stationary for two minutes and then thereafter as updating images are acquired. The smallest motion and the spatial alignment of the images is lost; the 3D image will then contain artifacts or be blurred. The eighteen 3D images used are below the limit of what is considered "live" imaging, which is about 20 frames per second. For reference, the frame rate of a US television set is 30 frames per second. Furthermore, the Strommer et al. approach assumes that the heart cycle does not change. This is a reasonable assumption for normal people, but individuals with heart problems or other disease states often exhibit a non-uniform heart rate in which the duration of the heart cycle changes from beat to beat. Since the 3D images are for a nominal heart cycle duration, a changing heart rate will produce an erratic display with different heart beats using different numbers of 3D images. Short heartbeats will appear to jump to the beginning of the next heartbeat as some of the 3D images are not used during the shorter duration ECG cycles, and longer heartbeats will spread out the 3D images in time and produce an erratic display. These are some of the reasons that Strommer et al. is referring to its display as a "pseudo real-time simulation" of the actual heart motion.

It is therefore respectfully submitted that for the reasons stated above the Strommer et al. application cannot anticipate any of independent Claims 1, 14, or 15, or their dependent Claims 2-5, 10-12, and 16-19. In addition, dependent Claim 11 calls for displaying a plurality of ECG traces related to the locations where the activity of the invasive medical device has been performed as exemplified in Fig. 16 of the present application. The Examiner points to the display of the ECG trace in Figs. 18 and 20 of Strommer et al. However, this is just the overall ECG waveform of the heart acquired by a standard ECG monitor 106 and described in paragraphs [0116] and [0117]. Claim 11 calls for a plurality of ECG traces related to the locations of the invasive activity. There is no relation to the ECG trace shown in Strommer et al. to any particular location of invasive activity. The Examiner points to the forward and backward buttons in Fig. 18 of Strommer et al. as depicting multiple ECG traces, but a reading of paragraphs [0250] and [0251] explains that these buttons are only for playing the recording of the single ECG trace and corresponding 3D images either backward or forward in time for post-procedure organ inspection.

Claims 6-9 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Strommer et al. in view of US Pat. 6,245,017 (Hashimoto). Hashimoto describe a system which displays 2D images time interleaved with 3D images. Like Strommer et al., the 3D image is assembled from a series of 2D image planes. Since the acquisition, processing and display of the 3D image takes so long which does not enable a smooth display of the motion in either image, the 2D image frame rate is improved by using images of the 3D acquisition to update the 2D display more rapidly than the 3D display. Hashimoto was cited for its showing of a "wire frame model" in its Fig. 12. But the rejected claims call for a real time wire frame model of an anatomical region within the volumetric region being imaged. Figs. 15 and 16 of the present application give the example of a real time wire frame model of the left ventricle of the heart. The wire frame model described by Hashimoto is seen in his Fig. 12 to be the contour of the 3D scan line pattern. For the probe shown at the top of his Fig. 12, this is the conical region in front of the probe in which the scan lines are produced. This region does not relate to any specific anatomy; the conical region is the same whether the probe is scanning the body or transmitting into the air. Furthermore, since this is the fixed region in front of the probe where the scan lines are produced, there is no real time aspect to this wire frame model. It is fixed for the probe and its scan pattern. For these reasons it is respectfully submitted that the combination of Strommer et al. and Hashimoto cannot render Claims 6-9 and 13 unpatentable.

To complete the citation of references, enclosed is an information disclosure statement and citation copies from a companion application, serial number 10/550,212. In that case the Examiner applied three patents to the pending claims. The Hunter et al. application shows a C-arm x-ray system in which an icon representing a catheter is superimposed over a pre-acquired 2D x-ray image of the body. In the Holupka et al. patent a probe is rapidly moved to acquire a series of 2D image slices of a 3D volume and specific image planes, preferably the transverse, coronal, and sagittal 2D views, are used to view needles and seed implants. In the Zanelli patent 3D image data is projected to create a 2-D projection plane image of the body and a catheter. The catheter is detected with the same ultrasound probe by vibrating it and detecting its signature by the Doppler sensitivity to its motion. It is respectfully submitted that the claims as amended above are patentable over the citations of this companion case.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1, 14, and 15 are clear and definite, that Claims 1-5, 10-12, and 14-19 are not anticipated by Strommer et al., and that Claims 6-9 and 13 are patentable over Strommer et al. and Hashimoto. Accordingly it is respectfully requested that the rejection of Claims 1, 14, and 15 under 35 U.S.C. §112, of Claims 1-5, 10-12, and 14-19 under 35 U.S.C. §102(e) and of Claims 6-9 and 13 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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